Food and Drug Administration, HHS

- (ii) Indications for use. For treatment of sheep respiratory disease (pneumonia) associated with M. haemolytica and P. multocida.
- (4) Goats—(i) Amount. 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.
- (ii) Indications for use. For treatment of caprine respiratory disease (goat pneumonia) associated with M. haemolytica and P. multocida.
- (5) Chickens—(i) Amount. 0.08 to 0.20 mg as a single subcutaneous injection in the neck.
- (ii) Indications for use. For control of early mortality associated with Escherichia coli organisms susceptible to ceftiofur in day-old chicks.
- (6) *Turkeys*—(i) *Amount*. 0.17 to 0.5 mg as a single subcutaneous injection in the neck.
- (ii) *Indications for use*. For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur in day-old poults.
- (7) Horses—(i) Amount. 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site.
- (ii) *Indications for use*. For treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus*.
- (iii) *Limitations*. Do not use in horses intended for human consumption.
- (8) Dogs—(i) Amount. 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared, for 5 to 14 days.
- (ii) *Indications for use*. For treatment of canine urinary tract infections associated with *E. coli* and *Proteus mirabilis*.

[53 5369, Feb. 24, 1988, as amended at 55 FR 13768, Apr. 12, 1990; 56 FR 12119, Mar. 22, 1991; 57 FR 41862, Sept. 14, 1992; 59 FR 41666, Aug. 15, 1994; 59 FR 54518, Nov. 1, 1994; 60 FR 51719, Oct. 3, 1995; 61 FR 35130, July 5, 1996; 61 FR 66583, Dec. 18, 1996; 66 FR 21283, Apr. 30, 2001; 66 FR 32540, June 15, 2001; 69 FR 47362, Aug. 52004. Redesignated and amended at 71 FR 39544, July 13, 2006; 74 FR 34236, July 15, 2009]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

- (a) [Reserved]
- (b)(1) Specifications. Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.
- (2) *Sponsor*. See No. 000856 in §510.600(c) of this chapter.
- (3) Conditions of use. (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.
- (ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.
- (iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 45 FR 16482, Mar. 14, 1980]

§ 522.390 Chloramphenicol injection.

- (a) Specifications. Each milliliter contains 100 milligrams of chloramphenicol.
- (b) *Sponsor*. See Nos. 000069 and 059130 in §510.600(c) of this chapter.
- (c) Conditions of use. Dogs—(1) Amount. 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.
- (2) Indications for use. Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsillitis caused by organisms susceptible to chloramphenicol.
- (3) Limitations. Not for use in animals raised for food production. Federal law

§ 522.460

restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000]

§ 522.460 Cloprostenol sodium.

- (a)(1) Specifications. Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.
- (2) *Sponsor*. See Nos. 000061 and 068504 in §510.600(c) of this chapter.
- (3) Conditions of use. For intramuscular use in beef and dairy cattle to induce luteolysis.
- (i) *Amount*. 2 milliliters (equivalent to 500 micrograms of cloprostenol).
- (ii) *Indications*. (a) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.
- (1) Single cloprostenol injection. Treat only animals with a mature corpus luteum. Estrus should occur in 2 to 5 days, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at 72 hours post injection or twice at 72 and 96 hours post injection.
- (2) Double cloprostenol injection. Give cattle a second injection 11 days after the first injection. Estrus should occur 2 to 5 days after the second injection, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at about 72 hours post injection or twice at 72 and 96 hours following the second injection.
- (b) Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception, or for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts.
- (c) Single cloprostenol injection for the treatment of pyometra.
- (iii) Do not administer to pregnant animals where the calf is not to be aborted.

- (iv) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.
- (v) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (b)(1) Specifications. Each milliliter of sterile aqueous solution contains 131.5 micrograms of cloprostenol sodium (equivalent to 125 micrograms of cloprostenol).
- (2) Sponsor. See No. 000061 in \$510.600(c) of this chapter.
- (3) Special considerations. Labeling shall bear the statements prescribed in paragraphs (a)(3) (iii) and (iv) of this section.
- (4) Conditions of use—(i) Amount. 3 milliliters (equivalent to 375 micrograms of cloprostenol) intramuscularly per animal as a single dose.
- (ii) Indications for use. To induce abortion in pregnant feedlot heifers from 1 week after mating until $4\frac{1}{2}$ months of gestation.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 4678, Feb. 2, 1982, as amended at 48 FR 15619, Apr. 12, 1983; 49 FR 5100, Feb. 10, 1984; 49 FR 29957, July 25, 1984; 65 FR 6892, Feb. 11, 2000; 69 FR 40766, July 7, 2004]

§ 522.468 Colistimethate sodium powder for injection.

- (a) Specifications. Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.
- (b) *Sponsor*. See 046573 in §510.600(c) of this chapter.
 - (c) [Reserved]
- (d) Conditions of use. (1) 1- to 3-day-old chickens.
- (i) Dosage. 0.2 milligram colistin activity per chicken.